

Serial No. 10/007,177
5962-01-CA

REMARKS

I. Status of the Application

This paper responds to a Final Office Action mailed on February 18, 2004 and subsequent Advisory Action mailed on June 4, 2004. The application was originally filed with 24 claims. In an amendment filed on October 25, 2002, Applicant canceled claims 8 and 13-16, and amended claims 1, 5, 9, 10, 17, 19 and 23. In response to a Final Office Action, Applicant canceled claims 1-7, 9-12, 22 and 24, and amended claims 17-21 and 23. A subsequent non-Final Office Action withdrew finality. In response to the non-Final Office Action, Applicant amended claims 17, 20, and 21. The present paper amends claim 17 and adds new claim 25. Accordingly, claims 17-21, 23, and 25 are under consideration in the present application.

Applicant respectfully requests reconsideration of the pending claims in view of the above amendment and the following remarks. By action taken here, Applicant in no way intends to surrender any range of equivalents beyond that needed to patentably distinguish the claimed invention as a whole over the prior art. Applicant expressly reserves all such equivalents that may fall in the range between Applicant's literal claim recitations and combinations taught or suggested by the prior art.

II. Response Within the First Month Following the Mailing date of the Advisory Action & Petition for a One-Month Extension of Time

Applicant hereby petitions for a one-month extension of time and submits the requisite fee. This paper responds to a Final Office Action that was mailed on February 18, 2004. Applicant filed an After Final Amendment on Monday, April 19, 2004, which was the first business day following the expiration date (Sunday, April 18, 2004) of the two-month period following the mailing date of the Final Office Action. Thus, the shortened statutory period for reply expired three months from the mailing date of the Advisory Action and not three months from the mailing date of the Final Office Action, as stated in the Advisory Action. The Advisory Action was mailed on June 4, 2004.

After Final Amendment Page 4 of 7

Serial No. 10/007,177
5962-01-CA

Applicant is filing this RCE and amendment on July 2, 2004, which is within the first month following the expiration of the shortened-statutory period for reply.

III. Supplemental Information Disclosure Statement

Applicant filed a supplemental information disclosure statement on November 15, 2002. Applicant has not received a copy of PTO/SB/08, which lists references cited in the supplemental information disclosure statement. Applicant respectfully requests that the next Office Action include a copy of the PTO/SB/08 form, which has been initialed by the Examiner. The references cited in the supplemental IDS included documents cited in a search report from the European Patent Office (EPO) for a corresponding patent application filed in the EPO.

IV. Amendment of Claim 17 and New Claim 25

Applicant has amended claim 17 to clarify that the recited dosage form is made by feeding components of the outer layer and the central core into first and second extruders, respectively, and coextruding an indefinite length of the at least partially melted central core and outer layer from the second and first extruders. New claim 25 recites that the first and second extruders are twin-screw extruders. The specification, as filed, fully supports new claim 25 and the changes to claim 17, and therefore Applicant submits that the present amendment introduces no new matter. See, for example, the Application at page 9, lines 5-27.

V. Rejection of Claims Under 35 U.S.C. § 102(b)/103(a)

The Office Action rejected claims 17-21 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Bar-Shalom et al. (US 5,618,560). Applicant submits that Bar-Shalom et al., either alone or in combination with other references cited in the case, does not teach or suggest every limitation of independent claim 17, and therefore does not render obvious the claimed invention. Applicant therefore submits that claim 17, as well as claims 18-21, 23, and 25, which depend on claim 17, are patentable over the prior art of record.

After Final Amendment Page 5 of 7

Serial No. 10/007,177
5962-01-CA

Claim 17 recites a method of making the pharmaceutical dosage form. In the claim, the pharmaceutical dosage form comprises a central core and a diffusion-limiting sleeve or outer layer. The central core has a pair of opposite end surfaces and a peripheral surface that extends between the opposite end surfaces. The diffusion-limiting sleeve, which is impervious to water or bodily fluids, surrounds the core's peripheral surface, but leaves the ends of the core exposed. As noted above, the pharmaceutical dosage form of the present application is formed by feeding components of the outer layer and the central core into first and second extruders, respectively, and coextruding an indefinite length of the at least partially melted central core and outer layer from the second and first extruders, resulting in a co-extrudate having an at least partially melted central core. The co-extrudate is subsequently cooled to solidify the at least partially melted central core and outer layer.

Bar-Shalom et al. discloses controlled release compositions comprised of an inner matrix and an outer coating. The controlled release compositions are prepared by separately mixing the components of the inner matrix and the components of the coating. The resulting inner matrix and coating compositions are subsequently fed to separate extruders to form the controlled release composition. See Bar-Shalom et al. at column 11, line 57-column 12, line 57 and the Examples. In contrast, the present application requires feeding the components of the outer layer and central core to extruders, which evidently are used to coextrude the central core and outer layer. Nothing in Bar-Shalom et al. teaches or suggests that the components of the two layers can be fed directly to the extruders. Furthermore, although Bar-Shalom et al. mentions coextrusion of the inner matrix and the coating, all of the examples describe extruding the inner matrix into a pre-formed tube of silicone or Teflon. Since the process described in Bar-Shalom is substantially different than the process claimed in the present application, Applicant submits that the claims of the present application are patentable over Bar-Shalom et al.

After Final Amendment Page 6 of 7

Serial No. 10/007,177
5962-01-CA

VI. Conclusion

In view of the foregoing, Applicant respectfully submits that all pending claims are patentable over the prior art of record. If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that any fees associated with the filing of the present amendment have been identified in a transmittal that accompanies this paper. However, if any fees are required in connection with the filing of this paper, and such fees have not been identified in the accompanying transmittal, please charge deposit account number 23-0455.

Respectfully submitted,

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After Final Amendment Page 7 of 7